National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Adverse Reaction (ADR) Form for Investigational Agents

Instructions: This form should be completed for all Adverse Reactions. It should be mailed according to the instructions of the Cooperative Group.

Patient's Initials: _____ Protocol No.: _____ Patient Sequence No.: _____

Institution/Affiliate: _____

Intergroup Protocol No.: _____ Intergroup Patient Sequence No.: _____

Name of treating physician: _____ Diagnosis: _____

Name of person completing this form: _____ Phone No.: _____

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☐☐ Toxicity grading criteria used (01 - Common toxicity criteria, 02 - Other/specify _____

☐☐ Toxicity category (01 -death, 02 -unusual, 03 -expected

☐ Treatment arm code

I. DEMOGRAPHICS

☐☐ ☐☐ Date of birth (M,Y) ☐☐ ☐☐ Date of initial diagnosis (M,Y)

☐☐ Sex (01=male, 02=female) ☐☐ ECOG Performance Status, day 1 of Rx

Please record site(s) of metastatic disease if appropriate (01=no, 02=yes, -1=unknown/not applicable)

☐☐ Nodal Involvement ☐☐ Osseous Involvement ☐☐ Visceral Involvement/specify: _____

☐☐ Was the patient taking non-protocol medications at the time of the ADR? (01=no, 02=yes, -1=unknown)

If yes, specify medications and any concurrent disease: _____

II. ADVERSE REACTION

Specify agent(s) suspected of causing reaction.

IF RELEVANT: _____

☐☐ Was any agent supplied by NCI? (01=no, 02=yes, -1=unknown

If no, specify source: _____

Specify toxicity type: _____

(e.g., cardiac, infection, or note if disease progression)

☐☐ Toxic grade of the ADR

☐☐ ☐☐ ☐☐ Date adverse reaction started (M, D, Y)

☐☐ ☐☐ ☐☐ Date adverse reaction ended (M, D, Y)

☐☐ ☐☐ ☐☐ Date protocol Rx started (M, D, Y)

☐☐ ☐☐ ☐☐ Date last dose of protocol (M, D, Y)

☐☐

☐☐ ☐☐ ☐☐ Date of Rx associated with the ADR (M, D, Y)

☐☐ ☐☐ ☐☐ Date of death (if patient died) (M, D, Y)

III. PRIOR TREATMENT Please list below any prior treatment for this malignancy (01=no, 02=yes, -1=unknown)

	Description	Start Date	Date End
☐☐ Prior chemotherapy/immunotherapy And/or hormonotherapy			
☐☐ Prior radiotherapy			
☐☐ Prior surgery			

IV. CURRENT PROTOCOL TREATMENT (include all agents)

Agent	Dose	Schedule	Route	Relation to ADR*	Action Taken**	Total Dose to Date

* Options–unrelated, unlikely, possible, probable, definite, unknown/not applicable.

** Action Taken–dose reduced, dose withheld, dose discontinued.

V. DOCUMENTATION OF REACTION *Please complete Part A and/or Part B*

Part A – Complete this section if the patient had either a non-hematologic reaction OR an unexpected hematologic reaction.

1. Give a brief description of the reaction and its temporal relationship to the Rx administration.

2. Give a brief description of any relevant physical findings or laboratory data which documents the ADR.

	Baseline: Date/Value	Nadir: Date/Value	Recovery or Most Recent: Date/Value
ADR Lab:	/	/	/

3. Give a brief description of how the ADR was treated.

4. Please list any complications and sequelae (if death, was autopsy done? Please submit report).

5. Please describe any medical history of the patient, which might be relevant to this event.

6. If the suspected agent(s) was given again, please describe dose and reactions.

Part B – Complete this section if the patient had a hematologic reaction – expected OR unexpected.

1. Laboratory Data Documenting ADR

	Baseline: Date/Value	Nadir: Date/Value	Recovery or Most Recent: Date/Value
ADR:	/	/	/
Platelets	/	/	/
HGB/HCT	/	/	/

2. Please give a brief description of any complications, treatment, and sequelae if Part A HAS NOT already been completed.

☐☐ ☐☐ ☐☐ Date telephoned Cooperative Group

☐☐ Reported to local IRB (01=no, 02=yes)

If relevant:

☐☐ ☐☐ ☐☐ Date form sent to Cooperative Group

☐☐ ☐☐ ☐☐ Date telephoned NCI (301-230-2330)

☐☐ ☐☐ ☐☐ Date form sent to NCI

Name of NCI contact: _____

☐☐ ☐☐ ☐☐ Date form sent to pharmaceutical company

☐☐ ☐☐ ☐☐ Date telephoned pharmaceutical company

☐☐ Report by

01=Institution

02=Statistical center ☐☐ ☐☐ ☐☐

03=Study chairman

04=Statistical center, but later documented as no report needed.

_____ **M.D.** _____

Signature of Responsible Physician ***Date***

Investigator: Keep a copy for your files and submit original form.